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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/971,774

Filing Date: October 09, 2001

Appellants: REDMOND et al.

Willem F. C. de Weerd
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 4, 2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

The brief states that Appellants are unaware of any other appeals and interferences related to the subject matter of the present appeal.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The Appellants' statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Claimed Subject Matter*

The summary of claimed subject matter contained in the brief is correct.

(6) *Grounds of Rejection to be Reviewed on Appeal*

The Appellants' statement of the grounds of rejection is correct.

(7) *ClaimsAppealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) *Prior Art of Record*

- JACOBI, C. A. et al. "Peritoneal installation of taurolidine and heparin for the prevention of intraperitoneal tumor growth and trocar metastases in laparoscopic operations using rats as a model" Langenbecks Arch. Chir. (1997) vol 382, suppl 1, pp 31-36.
- Physicians' Desk Reference (1995) Entry for 5-Fluorouracil, pp 2034-5.

WO 92/00743	MONSON et al	1-1992
5,262,403	NICOLSON et al	11-1993
5,176,651	ALLGOOD et al	1-1993

(9) *Grounds of Rejection*

The following grounds of rejection are applicable to the appealed claims:

Claims 1-5, 8, 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743).

The claims are drawn to a method of treating abdominal cancer comprising performing surgery to remove a cancerous tumor wherein the method includes a step of administering a solution of taurolidine and/or taurultam to the patient's abdomen prior to closing surgical opening along with an additional step of administering taurolidine and/or taurultam after closing surgical opening. Dependents are drawn to further limitations concerning the administration of the taurolidine/taurultam solution - administration before surgery, mode of administration, concentration of the solution, administration of other components, and types of cancers.

JACOBI teaches that the intraperitoneal administration of taurolidine or a combination of taurolidine and heparin at the time of laparoscopic surgery for tumor removal reduces the incidence of tumor growth and trocar metastases. See abstract. The reference discloses that lavage with taurolidine and heparin is performed in human patients undergoing laparoscopic resection of malignancies. See last paragraph of the reference on page S35. The reference does not explicitly describe each and every step in such a procedure. However, one of ordinary skill

would readily understand that performing such a procedure would implicitly include the steps of (1) forming a surgical opening; (2) removing cancerous tumor; (3) administering taurolidine prior to closing; and (4) closing the surgical opening. The reference is silent regarding the location of surgery, but the experimental section of the reference is drawn to colon adenocarcinoma in rats, so abdominal surgery is clearly suggested.

In this discussion of the laparoscopic procedure in human patients, the reference does not explicitly describe the use of a trocar in this procedure in this passage. However, the reference is drawn to the decreased incidence of trocar metastases, so the use of this instrument is clearly implied.

The reference does not teach the use of taurultam in the concentration range recited in this procedure or the use such a solution before surgery or after closing – step (5). Neither does the reference specifically address the full range of cancer types recited in the claims.

MONSON teaches that taurolidine and taurultam are functional equivalents as both antibacterials and *antitumorals*. See all of page 1. The reference further teaches that the agents are particularly beneficial for the prevention of the spread of metastases, especially following surgical removal of tumors of any type, including lymphomas, sarcomas, melanomas, and carcinomas. See page 3, second paragraph. The reference states “[i]t is particularly beneficial to use taurolidine and/or taurultam [to] prevent the spread of metastases, *especially following surgical removal of tumours.*” (Emphasis added) Therefore, patients in need of metastasis prevention would include those scheduled for cancer surgery and those who have had cancer surgery. The reference teaches administration of the solution by injection or infusion.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer a solution of taurolidine and/or taurultam (with or without heparin) during laparoscopic abdominal cancer surgery. MONSON had taught that these species (taurolidine and/or taurultam) are functional equivalents for the inhibition of metastases. In the absence of unexpected results, one of ordinary skill would reasonably expect success in the use of taurolidine and/or taurultam for this art-disclosed utility. It would be within the scope of the artisan to optimize the solution concentration with routine experimentation.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer a solution of taurolidine and/or taurultam before and/or after cancer surgery for the benefits of treating malignancies as well as prevention of metastases, taught by MONSON. In the absence of unexpected results, it would be further obvious to use this procedure for all of the recited cancers with a reasonable expectation of success. It would be within the scope of the artisan to select any common type of administration, such as IV or catheter, to administer the solution.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743) and further in view of ALLGOOD et al (US 5,176,651).

The invention is as set forth above. Claims 6, 7, and 10 are drawn to the use of a trocar comprising passing the taurolidine and/or taurultam solution through said trocar.

JACOBI and MONSON teach as set forth above. The references are silent regarding the administration of the taurolidine and/or taurultam solution by passing it through a trocar but does clearly suggest the use of a trocar for performing the surgical procedure.

ALLGOOD presents a brief discussion of the use of trocars and cannulas in endoscopic (laparoscopic) surgery. See col 1, lines 10-39. The reference teaches that laparoscopy typically comprises the use of a cannula inserted through a trocar for irrigation of the surgical site. By definition, irrigation comprises administration of a fluid to said site.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer taurolidine and/or taurultam in the JACOBI procedure via a cannula inserted through the trocar, as JACOBI had taught that the administration of the solution is beneficial in the prevention of trocar metastases. Fluid delivery via a cannula through a trocar in laparoscopy is standard procedure, as would be known to one of ordinary skill.

Claims 1-5, 8, 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743) and further in view of NICOLSON et al (US 5,262,403).

The invention is as set forth above. Claim 9 is drawn to the use of hyaluronic acid in combination with the taurolidine and/or taurultam.

JACOBI and MONSON teach as set forth above. The references teach the administration of the taurolidine and/or taurultam solution in combination with heparin but not hyaluronic acid.

NICOLSON teaches that glycosaminoglycans, such as heparin and hyaluronic acid, are useful for the inhibition of tumor-invasiveness and metastasis. See abstract and col 10, lines 4-10.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer the taurolidine and/or taurultam in combination with hyaluronic acid. JACOBI had taught that the administration of the taurolidine and/or taurultam in combination with heparin has utility in the prevention of metastasis. NICOLSON had taught that hyaluronic acid and heparin are functional equivalents for this utility. In the absence of unexpected results, one of ordinary skill would reasonably expect success in using hyaluronic acid in the JACOBI process.

Claims 1-5, 8, 9, 11, 12, and 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743) and further in view of PHYSICIANS' DESK REFERENCE (PDR - 1995).

The invention is as set forth above. Claim 26 is drawn to the method further comprising administration of 5-FU at a dosage of about 0.1-1,000 mg.

JACOBI and MONSON teach as set forth above. The references do not teach the method further comprising administration of 5-FU. However, MONSON expressly suggests the administration of taurolidine and/or taurultam in combination with other anti-tumor therapeutics. See page 3, lines 1-7.

PDR teaches that 5-FU has utility in the treatment of a variety of the recited cancers, including colon, rectum, breast, and stomach. The suggested dosage is about 500 mg/day.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the administration of a known anti-tumor therapeutic agent, such as 5-FU to the method of JACOBI for the further treatment of cancer. In the absence of unexpected results, it would have been within the scope of the artisan to select any known anti-cancer agent for the combination of benefits.

(10) *Response to Argument*

Claims 1-5, 8, 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743).

At page 6, 1st full paragraph, of the appeal brief, Appellants contend that the combination of references cannot be combined to suggest the particular steps of the method. First of all, the rejection outlines why one of ordinary skill would be motivated to combine these references to arrive at the present method, but Appellants fail to state why the combination of references is invalid. Secondly, Appellants fail to point out exactly which step(s) is/are not taught by the combination.

In response to Appellants' argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

At page 7, 1st full paragraph, Appellants again state that the prior art does not teach all the steps of the method. However, this passage addresses only JACOBI when the rejection is based on a combination of references.

Finally, Appellants allege that the combination of references does not teach the embodiment wherein taurolidine and/or taurultam is administered prior to forming a surgical opening. However, this embodiment was specifically addressed in the rejection. See page 4, last paragraph, of this action.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743) and further in view of ALLGOOD et al (US 5,176,651).

Appellants state that Allgood “merely discusses endoscopic surgery, but cannot be combined with Jacobi et al. and Monson et al.” The examiner agrees that Allgood discusses endoscopic surgery, but that is exactly why it is proper to combine Allgood with Jacobi and Monson. Jacobi is drawn to endoscopic (laparoscopic) surgery, and Allgood discusses typical methods known in the art.

Appellants further note that the Allgood disclosure includes the description of a sealing means in the trocar to prevent the flow of fluid. However, the reference was used only for its general teaching regarding the use of trocars in endoscopic surgery. “The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain.” In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting

In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). In the present case, the particular use of a trocar in Allgood's disclosure is not germane.

Claims 1-5, 8, 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743) and further in view of NICOLSON et al (US 5,262,403).

Claims 1-5, 8, 9, 11, 12, and 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743) and further in view of PHYSICIANS' DESK REFERENCE (PDR - 1995).

Appellant submits no new arguments not already addressed above.

In summary, the instant claims are drawn to a method for the surgical treatment of abdominal cancer with a series of typical surgical steps along with the administration of taurolidine and/or taurultam at various points in time with respect to the actual surgery. The main references JACOBI and MONSON in combination clearly teach this method as outlined above. Embodiments recited in dependent claims are addressed by the addition of one of ALLGOOD, NICOLSON or PDR. The teachings of these references would make this method obvious to one of ordinary skill.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

LCM
January 11, 2005

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